



# PARTICIPANT INFORMATION SHEET

The Effectiveness of Nutrition and Physical Activity Intervention on Psychosocial Well-Being of Mothers with Preterm Infants in Selangor

## NAME OF INVESTIGATORS:

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## **Participant Information Sheet**

### **Research Title**

The Effectiveness of Nutrition and Physical Activity Intervention on Psychosocial Well-Being of Mothers with Preterm Infants in Selangor

### **Introduction of Research**

The numbers of preterm birth are increasing in Malaysia. Due to prematurity, most of the infant will be admitted to NICU, and the NICU stays is eventually a traumatic event for parents. In addition, in Malaysia, postpartum care is highly influenced by cultural beliefs and practices. As it was a belief that postpartum women are weak, fragile and vulnerable to disease, women were informed of taboos such as to remain at home and avoid certain food. Previous reviews indicated that nutrition and physical intervention had effectively improved depressive symptoms. To the best of our knowledge, intervention to improve depression via a non-pharmacological approach among postpartum mothers has not been extensively explored in Malaysia.

### **Purpose of Research**

This study aims to determine the effectiveness of nutrition and physical activity intervention module on the psychosocial well-being of postpartum mothers with preterm infants

### **Research Procedure**

If you agree to participate, kindly give your informed consent. The following procedures as follows:

1. You will be enrolled either in a program named 'MomEENS' program, an intervention programme module or a standard postpartum healthcare.
2. You will be follow up for 8 weeks. The researcher will set an appointment to meet you during baseline, week 4 and week 8.
3. A few set of measurements will be done throughout the program:
  - i. **Anthropometry measurement (measurement of weight, height and waist measurement)**  
You are required to open your shoes for measurement of height and weight.
  - ii. **A set of self-administered questionnaire**  
You will be given a set of questionnaires. The questionnaires include personal and demographic profiles, mental health, confinement practice, dietary intake, and breastfeeding questionnaire.

We estimate the session to be completed all the measurements and questionnaires in about one hour. We also may need your prenatal book record for further information.

## **Intervention Procedure**

1. You will be asked to follow the intervention program, which will require you to modify nutrition intake and perform physical activity.
2. The intervention program will be last for eight weeks, with regular follow up from the researcher to monitor the progress throughout the intervention.
3. There will be no follow up after the you had finished the eight weeks intervention program.

## **Participation in Research**

Your participation in this research is entirely voluntary. You may refuse to take part in the study or you may withdraw yourself from participation in the research at any time without penalty.

## **Benefit of Research**

Information obtained from this study will benefit the researchers, Government of Malaysia, doctors and individuals for the advancement of knowledge and practice of medicine in future. As for the participants, this projects will help the participants to improve their psychosocial well-being.

If you have any question about this study or your rights, please contact the investigator at listed below:

Dr. Nur Islami bt Mohd Fahmi Teng, FSK UiTM (017-2471223)

Ms. Noor Fairuzi Suhana, FSK UiTM (013-2842003)

The Secretary, Medical Research and Ethics Committee, Ministry of Health Malaysia (03 33628407/8205/8888)

The investigator will inform you in a timely manner about any new findings or changes about the study which may affect your health or willingness to continue in this study. Where necessary, you may be asked to re-consent to participate.

## **Research Risk**

There may be risk of injury due to the physical exercise regime depending on how much exercise is being done. However, all the physical exercise provided was proven among the low-intensity exercise, and safety advice will be given before beginning each exercise.

## **Confidentiality**

Your medical information will be kept confidential by the investigators and will not be made public unless disclosure is required by law. When publishing or presenting the study results, your identity will not be revealed without your expressed consent. Only investigators in this study will have access to the study data. Each participant's form will be stored in the secure location in the research lab. The study data will be kept for 7 years after the publication and will be deleted after that.

By signing this consent form, you will authorize the review of records, analysis and use of the data arising from this study.

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Consent Form

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To become a subject in the research, you are advised to sign this Consent Form.

I herewith confirm that I have met the requirement of age and am capable of acting on behalf of myself as follows:

1. I understand the nature and scope of the research being undertaken.
2. I have read and understood all the terms and conditions of my participation in the research.
3. All my questions relating to this research and my participation therein have been answered to my satisfaction.
4. I voluntarily agree to take part in this research, to follow the study procedures and to provide all necessary information to the investigators as requested.
5. I may at any time choose to withdraw from this research without giving reasons.
6. I have received a copy of the Subjects Information Sheet and Consent Form.
7. Except for damages resulting from negligent or malicious conduct of the researcher(s), I hereby release and discharge UiTM and all participating researchers from all liability associated with, arising out of, or related to my participation and agree to hold them harmless from any harm or loss that may be incurred by me due to my participation in the research.

Subect's name : \_\_\_\_\_

MyKad no : \_\_\_\_\_

Signature : \_\_\_\_\_

Date : \_\_\_\_\_

Researcher's name : \_\_\_\_\_

MyKad no : \_\_\_\_\_

Signature : \_\_\_\_\_

Date : \_\_\_\_\_